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10/585,635	07/11/2006	Anna Quattropani	293065US0PCT	8529

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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09/10/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 10/585,635	Applicant(s) QUATTROPANI ET AL.	
	Examiner Laura L. Stockton, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-15 and 17-27 is/are pending in the application.
4a) Of the above claim(s) 18-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2-15, 17, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 2-15 and 17-27 are pending in the application.

This Office Action supersedes the Office Action dated August 16, 2010 and is necessary because a cited prior art reference {Chemical Abstracts Registry Number 368857-79-8, indexed in the Registry file on STN CAS ONLINE November 12, 2001} applied against the current pending claims was missing from Form PTO-892 dated August 16, 2010.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of

the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 28, 2010 has been entered.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-17 and 26 - drawn to products of formula (I) wherein X is S) in the reply filed on July 15, 2009 was acknowledged in a previous Office Action. The requirement was deemed proper and therefore made FINAL in the previous Office Action.

Subject matter not embraced by elected Group I and Claims 18-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the

restriction (election) requirement in the reply filed on July 15, 2009.

The rejections made in the previous Office Action that do not appear below have been overcome by Applicant's amendments to the claims. Therefore, arguments pertaining to these rejections will not be addressed.

Claim Objections

Claim 8 is objected to for being substantial duplicate of claim 7. Claim 13 is objected to for being substantial duplicate of claim 12. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a

substantial duplicate of the allowed claim. M.P.E.P.
§706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph
of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-15, 26 and 27 are rejected under 35
U.S.C. 112, first paragraph, as failing to comply with
the written description requirement. The claim(s)
contains subject matter which was not described in the
specification in such a way as to reasonably convey to
one skilled in the relevant art that the inventor(s),
at the time the application was filed, had possession
of the claimed invention.

This is a new matter rejection. There is no
support in the original filed specification or the
original filed claims for the R⁶ variable representing

"phenyl substituted by carboxy" in currently amended claim 2. Applicant states that support could be found on pages 19-22 of the instant specification, however, no sufficient support could be found. Further, newly added claim 27 list numerous species in which Applicant states is a re-presentation of original claim 6. However, original claim 6 did not list species. Applicant should specifically point out the support for any amendments {i.e., page number(s) and line number(s) for each species listed in newly presented claim 27}. See M.P.E.P. §§ 714.02 and 2163.06. Therefore, the claims lack written description as such.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite because claim 9 depends from cancelled claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-5, 7, 8, 11-14, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by:

a) Inaba et al. {JP 2002/53566 A} - Compounds 154 and 155 (reproduced below) on page 31 of 84 of the previously supplied English translation of JP 2002/53566;

b) Chemical Abstracts Registry Number 472981-38-7 {indexed in the Registry file on STN CAS ONLINE November 11, 2002};

c) Chemical Abstracts Registry Number 472981-15-0 {indexed in the Registry file on STN CAS ONLINE November 11, 2002};

d) Chemical Abstracts Registry Number 472981-35-4 {indexed in the Registry file on STN CAS ONLINE November 11, 2002};

e) Chemical Abstracts Registry Number 472980-03-3 {indexed in the Registry file on STN CAS ONLINE November 11, 2002};

f) Chemical Abstracts Registry Number 472979-69-4 {indexed in the Registry file on STN CAS ONLINE November 11, 2002};

g) Chemical Abstracts Registry Number 472979-32-1
{indexed in the Registry file on STN CAS ONLINE
November 11, 2002;

h) Chemical Abstracts Registry Number 472979-29-6
{indexed in the Registry file on STN CAS ONLINE
November 11, 2002;

i) Chemical Abstracts Registry Number 472979-27-4
{indexed in the Registry file on STN CAS ONLINE
November 11, 2002;

j) Chemical Abstracts Registry Number 472979-26-3
{indexed in the Registry file on STN CAS ONLINE
November 11, 2002;

k) Chemical Abstracts Registry Number 471915-18-1
{indexed in the Registry file on STN CAS ONLINE
November 8, 2002;

l) Chemical Abstracts Registry Number 471915-13-6
{indexed in the Registry file on STN CAS ONLINE
November 8, 2002;

m) Chemical Abstracts Registry Number 412919-82-5
{indexed in the Registry file on STN CAS ONLINE
May 9, 2002;

n) Chemical Abstracts Registry Number 368859-44-3
{indexed in the Registry file on STN CAS ONLINE
November 12, 2001;

o) Chemical Abstracts Registry Number 368857-86-7
{indexed in the Registry file on STN CAS ONLINE
November 12, 2001;

p) Chemical Abstracts Registry Number 368857-84-5
{indexed in the Registry file on STN CAS ONLINE
November 12, 2001;

q) Chemical Abstracts Registry Number 368857-82-3
{indexed in the Registry file on STN CAS ONLINE
November 12, 2001]; or

r) Chemical Abstracts Registry Number 368857-79-8
{indexed in the Registry file on STN CAS ONLINE
November 12, 2001.

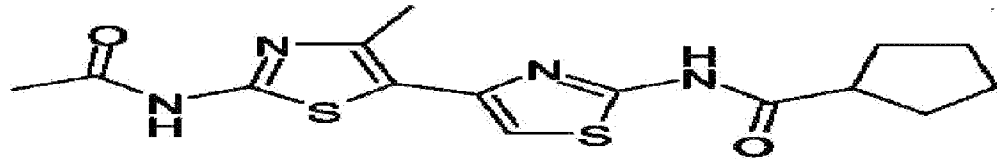
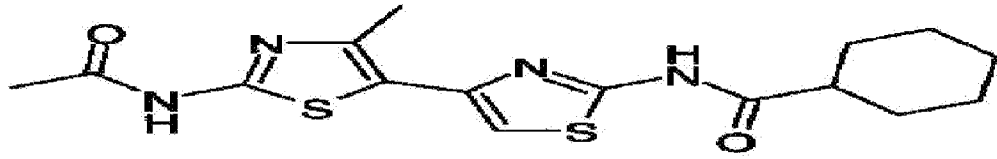
Each of the above cited prior art disclose at least one compound which is embraced by the instant claimed invention. Note on page 18, lines 18-25, of the instant specification, it states that the compounds of Formula (I) embrace pharmaceutical acceptable salts of compounds of Formula (I). Therefore, each of the above cited prior art anticipates the instant claimed invention.

Response to Arguments

Applicant's arguments filed July 28, 2010 have been fully considered but they are not persuasive. Applicant argues that Compounds 5 and 6 of Inaba et al. are not embraced by the currently amended claimed invention.

In response, it is agreed that Compounds 5 and 6 of Inaba et al. are not embraced by the instant currently amended claimed invention. However, the previous Office Action stated "for example" Compounds 5 and 6.

Therefore, there were additional compounds in Inaba et al. which anticipated the claimed invention. Compounds 154 and 155 (reproduced below)

154	 C15H18N4O2S2
155	 C16H20N4O2S2

are embraced by the instant currently amended claims when R^1 is $-NR^5R^6$; R^5 is hydrogen; R^6 is C_1 - C_6 alkyl C_3 - C_8 cycloalkyl; R^2 is H; R^3 is C_1 - C_6 alkyl; R^4 is C_1 - C_6 alkyl; and X is S. Note that on page 16, lines 20-28, of the instant specification (reproduced below),

20 "Substituted or unsubstituted": Unless otherwise constrained by the definition of the individual substituent, the above set out groups, like "alkenyl", "alkynyl", "aryl", "heteroaryl", "cycloalkyl", "heterocycloalkyl" etc. groups can optionally be substituted with from 1 to 5 substituents selected from the group consisting of "C₁-C₆-alkyl", "C₂-C₆-alkenyl", "C₂-C₆-alkynyl", "cycloalkyl", "heterocycloalkyl", "C₁-C₆-alkyl aryl", "C₁-C₆-alkyl heteroaryl",
25 "C₁-C₆-alkyl cycloalkyl", "C₁-C₆-alkyl heterocycloalkyl", "amino", "ammonium", "acyl", "acyloxy", "acylamino", "aminocarbonyl", "alkoxycarbonyl", "ureido", "aryl", "carbamate", "heteroaryl", "sulfinyl", "sulfonyl", "alkoxy", "sulfanyl", "halogen", "carboxy", trihalomethyl, cyano, hydroxy, mercapto, nitro, and the like.

the substituent groups embrace unsubstituted or substituted unless otherwise constrained. Therefore, the R⁶ variable position of Compounds 154 and 155 is a cycloalkyl-carbonyl wherein the instant C₁-C₆ alkyl C₃-C₈ cycloalkyl substituent, defined by R⁶, is a substituted alkyl (i.e., an alkyl substituted with an oxo). Therefore, Inaba et al. anticipate the instant currently amended claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-15, 17, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba et al. {JP 2002/53566 A}, Wu et al. {WO 2006/050351 A2} and Takaya et al. {U.S. Patent 4,649,146}, each taken alone. An English translation has been provided of the JP document with a previous Office Action and will be referred to hereinafter.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims thiazole compounds. **Inaba et al.** (see entire document; particularly page ii of 48 thru page 16 of 48, page 25 of 48 thru page 26 of 48; and

especially Compounds 154 and 155 on page 31 of 84), **Wu et al.** (see entire document; particularly pages 4, 5, 7 and 10-12, and Formula Ic on page 5; and especially Compound Number 2 in Table 1 on page 18) and **Takaya et al.** (see entire document; particularly column 1; formula [Ik] at the top of column 5, lines 1-5; column 11, lines 28-33; column 12, lines 41-45; and especially Examples 85 and 87 in column 46 and Compound 123 in column 55) each teach thiazole compounds that are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)

The difference between some of the thiazole compounds of the prior art and the compounds instantly claimed is that the instant claimed thiazole compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP
§2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (C.C.P.A. 1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., protein kinase Cγ inhibitors).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful as, for example, a pain killer. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

At the very least, such renders at bar obvious as regards these structured compounds and, as regards homologous, isomeric, or other "similar" compounds encompassed in the claims, such are obvious, under 35

U.S.C. § 103 over said reference compounds. In order to establish patentability, there must at least be a comparative showing establishing distinguishing characteristics allegedly showing that claimed compounds are unobvious.

Response to Arguments

Applicant's arguments filed July 28, 2010 have been fully considered but they are not persuasive. Applicant argues that there is no evidence of record supporting the conclusion made by the Examiner that "the expectation of obtaining additional beneficial products which would be useful as, for example, a pain killer." Applicant alleges that differences in structure lead to different activities. Applicant also argues that the compounds of Inaba et al. and compounds 1 and 2 of Wu et al. are structurally different from the instant claimed compounds.

All of Applicant's arguments have been considered but have not been found persuasive. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Each of the factual set forth in *Graham v. John Deere Co.* have been addressed in the above 35 USC 103 rejection. Applicant argues that there is no evidence

of record supporting the conclusion made by the Examiner that "the expectation of obtaining additional beneficial products which would be useful as, for example, a pain killer." In response, it is disagree that there is no evidence of record to support expectation of success. The evidence is supplied by the cited prior art references. MPEP 2143.02 states the following:

2143.02 [R-6] Reasonable Expectation of Success Is Required

>A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 (2007); *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson 's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

**I. < OBVIOUSNESS REQUIRES ONLY A REASONABLE EXPECTATION
OF SUCCESS**

The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (Claims directed to a method of treating depression with amitriptyline (or nontoxic salts thereof) were rejected as *prima facie* obvious over prior art disclosures that amitriptyline is a compound known to possess psychotropic properties and that imipramine is a structurally similar psychotropic compound known to possess antidepressive properties, in view of prior art suggesting the aforementioned compounds would be expected to have similar activity because the structural difference between the compounds involves a known bioisosteric replacement and because a research paper comparing the pharmacological properties of these two compounds suggested clinical testing of amitriptyline as an antidepressant. The court sustained the rejection, finding that the teachings of the prior art provide a sufficient basis for a reasonable expectation of success.); *Ex parte Blanc*, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989) (Claims were directed to a process of sterilizing a polyolefinic

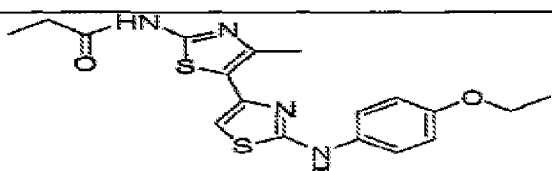
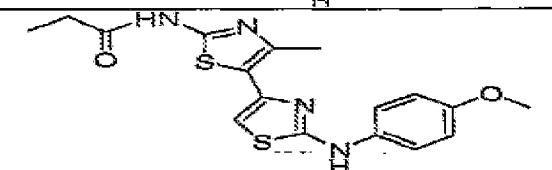
Therefore, the burden is shifted to Applicant and Applicant must present persuasive evidence showing that there was no reasonable expectation of success and that differences in structure lead to different activities.

Applicant also argues that the compounds of Inaba et al. In response, Inaba et al. disclose compounds that anticipate the instant claimed compounds as well as make obvious other compounds instantly claimed. See above explanation under 35 USC 102(b). Therefore, there is no difference between some of the compounds

disclosed in Inaba et al. and the instant claimed compounds.

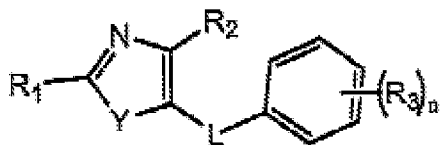
Further, and as stated in the previous Office Action, it is agreed that Wu et al. and Takaya et al. generically teach the instant claimed compounds. However, the teaching in Wu et al. and Takaya et al. would lead one skilled in the art toward the instant claimed compounds. Note, the specific designations in each cited prior art reference detailed above. For example, Compound Number 2 in Table 1 on page 18 of Wu et al. (reproduced below)

Table 1

Compound Number	Structure
1	
2	

differs from the instant claimed invention in that the methoxy group on the phenyl ring (Wu et al.'s R₃

variable) is in the **4**-position instead of the **2**- or **3**-position of the phenyl ring as instantly claimed (see instant R⁶ definition). However, Wu et al. teach that substituents represented by their R₃ variable can be variably attached to the phenyl ring. See the formula on page 4, paragraph [0010] of Wu et al.,



. Additionally, as stated in Ex parte Weston, 121 USPQ 428 (Bd. Pat. App. & Int. 1958), the original admission of equivalency in the specification (page 20, lines 6-8) and the originally filed claims of a 2-methoxyphenyl group or 3-methoxyphenyl group and a methoxyphenyl group broadly at the instant R⁶ variable position does not make Applicant's argument persuasive for the patentability of a 2-methoxyphenyl group or 3-methoxyphenyl group over a methoxyphenyl group broadly (which embraces the 4-methoxyphenyl group) because Applicant has already

disclosed and claimed that the methoxyphenyl group, regardless of the position of the methoxy on the phenyl ring, are equivalents.

As stated in the previous Office Action, there is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. In re Dillon, 16 U.S.P.Q. 2d 1897, 1904 (Fed. Cir. 1990). For all the reasons stated above, the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/
Laura L. Stockton, Ph.D.
Primary Examiner, Art Unit 1626
Work Group 1620
Technology Center 1600

September 8, 2010